DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2015

ArtVentive Medical Group, Inc.
% Roberta Hines
Northwest Clinical Research Group, Inc.
19836 NE 125th Place
Woodinville, WA 98077

Re: K150402
Trade/Device Name: Endoluminal Occlusion System (EOS)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 25, 2015
Received: August 27, 2015

Dear Ms. Hines:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150402

Device Name
Endoluminal Occlusion System (EOS)

Indications for Use *(Describe)*
The ArtVentive Endoluminal Occlusion System (EOS) is intended for arterial and venous embolization in the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 (Summary):

A summary of the information regarding the safety and effectiveness of the ArtVentive Medical Group Endoluminal Occlusion System (AVMG EOS™), as required by the Safe Medical Device Amendments of 1990, is provided as follows:

510(k) Summary for the
ArtVentive Medical Group Endoluminal Occlusion System™

1. Applicant:	ArtVentive Medical Group, Inc.
2. Address:	ArtVentive Medical Group, Inc. 2766 Gateway Road Carlsbad, CA 92009
3. Sponsor Contact Person:	Leon Rudakov, PhD., President and CTO
4. Telephone: **E-mail:**	650-465-5259 leonrudakov@artventivemedical.com
5. 510(k) Summary Preparation Date:	February 9, 2015
6. Device Trade Name:	Endoluminal Occlusion System (EOS)™
7. Common Name:	Vascular Embolization Device
8. Classification Name:	Device Embolization, Vascular (21 CFR 870.3300, Product Code: KRD)
9. Legally Marketed Predicate Devices:	ArtVentive Medical Endoluminal Occlusion System (EOS)™

10. Description of the ArtVentive Medical Group - Endoluminal Occlusion System (EOS™):
The ArtVentive Medical Group Endoluminal Occlusion System™ (AVMG EOS™) has been developed for arterial and venous embolizations in the peripheral vasculature. The system consists of three major components: a preloaded implant, the delivery catheter, and the guide catheter with dilator. The AVMG EOS™ is intended for single use only.

Like the parent ArtVentive Endoluminal Occlusion System – EOS, the proposed 11mm size of the device is comprised of an implant made of a Nitinol coil scaffold with an ePTFE occlusion membrane

and is designed with radial force sufficient to provide stiffness and strength against the vessel wall and minimize post-deployment migration. The delivery system is made up of a delivery catheter and the guide catheter with dilator. The implant delivery catheter contains one implant loaded on the distal end and a deployment handle on the proximal end connected by the shaft. The delivery catheter has a low profile and is flexible to allow for trackability and pushability. The implant itself and the catheter's distal end are visible under fluoroscopy.

The guide catheter is a braided shaft with a stiff proximal section and a more flexible distal section to enable tracking through tortuous peripheral vasculature. A radiopaque marker on the distal end of the catheter is visible under fluoroscopy. The tip of the guide catheter is tapered to fit over the dilator. The dilator fits inside the guide catheter exiting out through the distal end. The dilator also has a tapered end for ease of advancement into the blood vessel. The guidewire and dilator are removed from the guide catheter once it is in position for delivery of the implant.

11. Comparison to Predicate Device:

Manufacturer / Device	**ArtVentive Medical Group, Inc./EOS**	**ArtVentive Medical Group, Inc./EOS**
510(k) Number	K150402	K133924
Application / Product Code	21 CFR 870.3300 (KRD)	21 CFR 870.3300 (KRD)
FDA Classification	Class II	Class II
Technological Characteristics		
Intended Use	The ArtVentive EOS™ is intended for arterial and venous embolizations in the peripheral vasculature.	The ArtVentive EOS™ is intended for arterial and venous embolizations in the peripheral vasculature.
Design Features	Flexible, low profile device for immediate, acute occlusion of the target vessel. The device incorporates an ePTFE cover. Retrievable; may be removed during deployment and re-positioned. Two-stage deployment handle on the proximal end. The catheter has a stiff proximal section for pushability and a flexible distal section for trackability. The deployment handle has a side port to accommodate syringe attachment to flush the catheter of air and to pre-expand the ePTFE membrane before deploying the implant.	Flexible, low profile device for immediate, acute occlusion of the target vessel. The device incorporates an ePTFE cover. Retrievable; may be removed during deployment and re-positioned. Two-stage deployment handle on the proximal end. The catheter has a stiff proximal section for pushability and a flexible distal section for trackability. The deployment handle has a side port to accommodate syringe attachment to flush the catheter of air and to pre-expand the ePTFE membrane before deploying the implant.
Material	Nitinol coil with an ePTFE polymeric cover	Nitinol coil with an ePTFE polymeric cover

Detachment	Mechanical in nature	Mechanical in nature
Sizes	Diameter (mm) Length (mm) 5 11 8 20 11 27 5mm diameter for target vessel diameter 3.0mm – 5.0mm 8mm diameter for target vessel diameter 4.5mm – 8.0mm 11mm diameter for target vessel diameter 7.5mm – 11mm	Diameter (mm) Length (mm) 5 11 8 20 5mm diameter for target vessel diameter 3.0mm – 5.0mm 8mm diameter for target vessel diameter 4.5mm – 8.0mm
Treatment Method	Permanent Implant	Permanent Implant
How Applied	Via delivery catheter through guide catheter to target vessel	Via delivery catheter through guide catheter to target vessel

12. Intended use of the ArtVentive Medical Group - Endoluminal Occlusion System (EOS)™:

The ArtVentive Medical Group Endoluminal Occlusion System™ (AVMG EOS™) is indicated for arterial and venous embolizations in the peripheral vasculature.

13. Performance Data:

Bench studies indicate that the ArtVentive Endoluminal Occlusion System with the 11mm size of the delivery catheter/implant and 7.5mm size of the guide catheter as well as with the minor design modifications made to the 5mm and 8mm parent devices perform as intended. The following testing was repeated for the additional sizes of the device: dimensional and functional design verification/validation, MRI compatibility, corrosion, and radial strength. The design verification and validation testing was repeated as necessary for the minor design modifications to the cleared 5mm and 8mm delivery catheter/implant and the 6 Fr guide catheter. The review of the technological characteristics, indications for use, and verification and validation information provided in the 510(k) Premarket Notification demonstrates that the ArtVentive Medical Group Endoluminal Occlusion System - EOS™ is substantially equivalent to its predicate device.

14. Substantial Equivalence:

The 11mm size of the delivery catheter/implant and 7.5 Fr size of the guide catheter of the ArtVentive Endoluminal Occlusion System – EOS™ are substantially equivalent to the predicate device when used according to its intended use. The equivalence was based on the information provided in this 510(k) Premarket Notification which demonstrates that these added sizes of the ArtVentive Endoluminal System share the same technological characteristics, mechanism of action, intended use and physical

characteristics when compared to its predicate. The minor design modifications made to the parent device in sizes 5mm and 8mm delivery catheter/implant and 6 Fr guide catheter are also substantially equivalent to the predicate device when used according to its intended use. The equivalence was based on repeating the applicable design verification and validation testing.